REMARKS

Claims 1-16, 18-77, and 113-130 are pending. Claims 27-35, 48-77, and 113-140 are withdrawn as directed to nonelected subject matter. Claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47 read on the elected species; claims 1-5, 7, 9, 11, 36-41 and 45 are withdrawn as directed to unelected species.

35 U.S.C. § 112 Rejections

Reconsideration is respectfully requested of the rejection of claims 1-4, 9-13, 15-20, 24, 26 and 30-37 under 35 U.S.C. § 112, first and second paragraphs for lack of enablement and indefiniteness. However, applicants believe that this rejection was intended by the Office to apply to claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47. Applicants reiterate that the specification discloses the manner and process of making biocathodes and biofuel cells as claimed, and that the Office has not shown that there is reason to doubt the objective truth of the statements made in the specification. In this case, applicants provide ample guidance in selection of each of the components of the claimed bioanode (e.g., electron conductors, electron mediators, electrocatalysts, enzymes, and enzyme immobilization materials) and discloses several examples of working bioanodes. Therefore, the specification must be taken as in compliance with the enablement requirement. Applicants cite *in re Marzocchi* wherein

> [as] a matter of Patent Office practice, a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.
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> . . .
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> It is incumbent on the Patent Office whenever a rejection [for enablement] is made, to explain *why* it doubts the truth or accuracy of any statement in the supporting disclosure and to back up such assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.[1]

[1] M.P.E.P. § 2164.04; *In re Marzocchi*, 169 U.S.P.Q. 367, 370 (C.C.P.A. 1971).

Moreover, in *U.S. v. Telectronics, Inc.*, the Federal Circuit held that the claims were enabled

> where the "claims literally comprehend numerous polymers in addition to the one specifically described in appellant's specification" because no persuasive reason was given by the Patent Office why the specification does not realistically enable one skilled in the art to practice the invention as broadly as it is claimed.[2]

The patent at issue was directed to a system for healing bone fractures by delivering a current to the fracture site. The exemplified system had a stainless steel cathode operating at 5-20 μA, but the claims were not limited to a specific metal/current combination. Similarly, the instant claims do not limit the enzyme immobilization material to the exemplified embodiment, the specification provides ample guidance regarding other materials that could be used as an enzyme immobilization material,[3] and the Office has not provided a persuasive reason why the specification does not realistically enable one skilled in the art to practice the invention.

Further, the bioanode components can function as follows. The electrons flow from the enzyme to the electrode, the bioanode comprises an electron conductor, a reduced form of an electron mediator capable of donating electrons to the electron conductor to produce an oxidized form of the electron mediator, an enzyme capable of reacting with the oxidized form of the electron mediator and an enzyme immobilization material comprising the electron mediator. When an electrocatalyst is used, a reduced form of the electrocatalyst donates electrons to the electron conductor to produce an oxidized form of the electrocatalyst and this oxidized form of the electrocatalyst reacts with a reduced form of an electron mediator. Claim 6 requires these reactions to occur and transport of the electron mediators and electrocatalysts through the immobilization material (e.g., membrane) allow these reactions to occur. Thus, claim 6 and the claims that depend therefrom satisfy 35 U.S.C. § 112, first paragraph and 35 U.S.C. § 112, second paragraph.

As indicated in an Office action dated October 6, 2008, applicants note that 35 U.S.C. § 112, first and second paragraph rejections of the claims for lack of enablement and indefiniteness were overcome in a response filed April 14, 2008 in U.S. Application No. 10/931,147. This application includes claims to biocathodes currently rejected under 35 U.S.C. § 112, first

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[2] *U.S. v. Telectronics, Inc.*, 8 U.S.P.Q.2d 1217, 1224 (Fed. Cir. 1988), quoting *In re Bowen*, 492 F.2d 859, 863, 181 U.S.P.Q. 48, 51-52 (C.C.P.A. 1974).

[3] See specification at paragraphs [0038]-[0040].

paragraph for lack of written description. It appears that this rejection was reviewed and copied for the instant application even though no written description rejection was of record in the instant application. Specifically, the examiner's language in the outstanding Office action seems to be directed to a lack of written description under 35 U.S.C. § 112, first paragraph by stating that "Applicant does not provide criteria that define the components of the bioanode" because the definitions of the enzyme and enzyme immobilization material do not provide structural, physical, or chemical properties of the components and cites several legal cases defining the written description requirement.[4] Thus, if the Office is asserting that claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47 fail to satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, applicants contend that this is a new ground of rejection and a final rejection is improper since the rejection was not necessitated by amendments made by applicant in its last response .

However, for argument's sake, applicants assert that claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. To that end, applicants direct the examiner to *Ex parte Poterie*,[5] a Board decision reversing the Office's rejection of claims under 35 U.S.C. § 112, first paragraph for failing to satisfy the written description requirement. The claims were essentially directed to a cosmetic composition comprising at least one film-forming polymer and at least one thermal transition agent that undergoes a change of state at a transition temperature, T_t, from 25°C to 80°C and is not soluble in water at a temperature below the transition temperature, T_t.

The Board stated that the first paragraph of § 112 does not require a description of the complete structure of every species within a chemical genus, but is satisfied when the specification recites "enough detail to allow a person of ordinary skill in the art to understand what is claimed and to recognize that the inventor invented what is claimed."[6] Moreover, it is the examiner's initial burden to establish why a person skilled in the art would not have recognized a description of the invention defined by the claims.[7] In *Poterie*, the examiner asserted that the disclosure of several species of polycaprolactones did not "provide evidence of possession" of the genus of semi-crystalline thermal transition agents and the claim did "little

[4] See Office action dated February 5, 2009 at pages 2-3.
[5] Appeal 2008-5435, Application No. 09/881,097 (attached).
[6] See id. at page 5, quoting *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 928 (Fed. Cir. 2004).
[7] See id. at page 6, quoting *In re Wertheim*, 541 F.2d 257, 263 (C.C.P.A. 1976).

more than define the claimed invention by function."[8] In response, applicants' asserted that an adequate written description requires a "precise definition, such as by structure, formula chemical name, or physical properties" and such a definition was present in the physical properties of (1) semi-crystalline nature, (2) transition temperature range, and (3) lack of water solubility below the transition temperature.[9] The Board agreed with applicants and found that the "[s]pecification reasonably conveys that polycaprolactones are merely examples of a larger genus of semi-crystalline thermal transition agents, defined by their physical properties, and whose physical properties make them suitable for the claimed compositions."[10]

Similar to the examiner's position in *Poterie*, the Office states that the definitions for the enzyme and enzyme immobilization material "do not provide structural, physical, or chemical properties of the components."[11] To the contrary, like the polycaprolactones of *Poterie*, the enzyme and enzyme immobilization material of claim 6 are part of the claimed biocathode and defined in terms of their physical and chemical properties. For example, the requirements that (1) the enzyme is capable of reacting with an oxidized form of an electron mediator and a fuel fluid to produce an oxidized form of the fuel fluid and a reduced form of the electron mediator, and (2) the stabilized enzyme retains at least about 75% of its initial catalytic activity for at least about 30 days are chemical properties of the enzyme. Further, the requirement of (3) the enzyme immobilization material immobilizing and stabilizing the enzyme, and (4) the enzyme immobilization material being permeable to the fuel fluid are physical properties of the enzyme immobilization material. Thus, contrary to the Office's position and similar to the *Poterie* claims, claim 6 is not "wholly" functional, but define these components of the bioanode according to their chemical and physical properties.

Although it is clear from *Poterie* that a structure-function relationship is not required for written description, there is a structure-function relationship between the physical property of the enzyme immobilization material of "immobilizing and stabilizing the enzyme" and the chemical property of the "stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days." The enzyme retains its activity for the specified time because it is stabilized (e.g., entrapped) by the enzyme immobilization material and is protected chemically

[8] See id. at page 6.
[9] See id. at page 6.
[10] See id. at page 7.
[11] See Office action dated February 5, 2009 at page 3.

by the buffering ability of the enzyme immobilization material and physically prevented from denaturing by enzyme unfolding.

Further, *in re Fuetterer*[12] and *in re Swinehart*[13] support applicants' assertion that the Office has not established a reason why a person skilled in the art would not have understood that applicants' possessed the claimed invention. In *Fuetterer*, the claims were essentially directed to a rubber stock for producing tire treads containing a base portion, a mixture of protein and carbohydrate, and an inorganic salt capable of holding a mixture of said carbohydrate and protein in colloidal suspension in water. These claims were rejected for being unduly broad and functional because "'inorganic salt' reads on literally thousands of materials, many of which would not be operative for applicant's purpose."[14] However, the C.C.P.A. responded that the desired result of Appellant's invention

> is limiting the skidding of a tire tread stock on a wet surface. Appellant, in the claims before us, is not claiming this result. A myriad of alternative means for achieving this result can be easily thought of which would not require the particular combination of substances claimed by appellant. Insofar, therefore, as a "functional" claim may mean one which covers all means of arriving at the desired result, although the means by which such result is obtained is entirely different from that disclosed by the applicant, it is apparent that appellant's claims are not "functional."[15]

Similarly, applicants' desired result for the invention is a biofuel cell having a longer lifetime. There are many alternative means for accomplishing this result without using applicants' claimed bioanode. Thus, claim 6 is not defined functionally if that term means a claim that covers all means of arriving at the desired result.

In *Swinehart*, the claims were directed to a composition of barium fluoride and calcium fluoride in approximately eutectic proportions being transparent to infra-red rays and resistant to thermal shock.[16] The C.C.P.A. held that transparency to infra-red rays did "not necessarily refer to a function of the recited composition or to a desired result but rather it define[d] a physical property."[17] Similarly, the elements of claim 6 recited above are not a function of the recited

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[12] 138 U.S.P.Q. 217 (C.C.P.A. 1963).
[13] 169 U.S.P.Q.226 (C.C.P.A. 1971).
[14] *In re Fuetterer* at 220.
[15] *Id.* at 221.
[16] *Swinehart* at 227.
[17] *Id.* at 228.

composition or a desired result, but rather chemical and physical properties of the components of the claimed bioanode.

The Office also appears to object to the use of functional language in defining the point of novelty of the claim, and the C.C.P.A. stressed that *such concerns are not only irrelevant, they are misplaced*:

> We take the characterization "functional", as used by the Patent Office . . . to indicate nothing more than the fact that an attempt is being made to define something (in this case, a composition) by what it *does* rather than by what it *is* (as evidenced by specific structure or material, for example). In our view, there is nothing intrinsically wrong with the use of such a technique in drafting patent claims. . . . We recognize that prior cases have hinted at a possible distinction in this area depending on the criticality of the particular point at which such language might appear. Our study of these cases has satisfied us, however, that any concern over the use of functional language at the so-called "point of novelty" stems largely from the fear that an applicant will attempt to distinguish over a reference disclosure by emphasizing a property or function which may not be mentioned by the reference and thereby assert that his claimed subject matter is novel. Such a concern is not only irrelevant, it is misplaced.[18]

The court went on to indicate that the Office has the authority to reject such claims as lacking novelty and require the applicant to prove that the subject matter in the prior art does not possess such a characteristic. During prosecution of the instant application, applicants have repeatedly shown that the chemical property of the "stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days" is not a characteristic of the cited references of record. Applicants submit that the Office's concern over the use of functional language at the so-called "point of novelty" is perpetuating the irrelevant and misplaced fear that the court warned against in *Swinehart*.

In sum, claim 6 and the claims that depend therefrom satisfy the requirements of the first and second paragraphs of 35 U.S.C. § 112.

35 U.S.C. § 103 Rejections

Reconsideration is requested of the rejection of claims 6, 8, 10, 12, 42-44 and 47 as unpatentable over Karyakin, claims 17-22 as being unpatentable over Karyakin in view of Jin, claims 6, 13-16 and 23-26 as being unpatentable over Zawodzinski in view of Gregg, and unspecified claims as being unpatentable over Zawodzinski in view of Gregg and Khan under 35

[18] *Swinehart* at 228-9.

U.S.C. § 103. Applicants note that the outstanding rejections do not give any patentable weight to the enzyme stabilization criteria in the pending claims (e.g., the stabilized enzyme retaining at least about 75% of its initial catalytic activity for at least about 30 days while continuously reacting with the electron mediator). While the element "at least about" in claim 6 would allow for retention of activity of somewhat less than 30 days, the magnitude of the difference in required retention of enzyme activity and the retention of enzyme activity demonstrated in the cited art is a critical aspect in determining the obviousness of claim 6. For example, claim 6 distinguishes the art of record because the cited references would have described or suggested an enzyme stability of only 13 hours upon continuous use as noted in applicants' last response. There are no circumstances wherein an enzyme stability of 13 hours would be interpreted to meet the "at least about 30 days" requirement and the Office's rejection based on such a contention is improper and has no basis in fact or law. Thus, claims 6, 8, 10, 12-16, 18-26, 42-44, 46 and 47 are patentable over the cited references for this reason and for the further reasons as described in detail in the previous response under 35 U.S.C. § 103.

Moreover, as indicated in an Office action dated October 6, 2008, applicants note that 35 U.S.C. § 103 rejections of the claims over the same references as cited herein were overcome in a response filed April 14, 2008 in U.S. Application No. 10/931,147.

Rejoinder

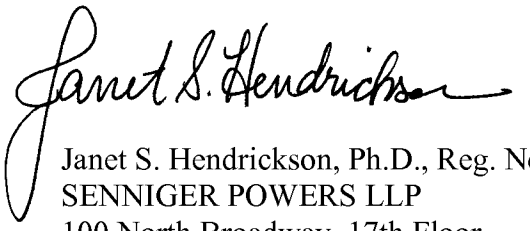
Pursuant to M.P.E.P. §821.04, applicants again request rejoinder of withdrawn claims 27-35, 49-52, 60-62, 114, and 117-130 as they depend from claim 6 and therefore require all the limitations of claim 6. Applicants further request reconsideration of withdrawn unelected species claims 1-5, 7, 9, 11, 36-41, and 45 because they either require all the limitations of claim 6 or overlap the scope of claim 6.

CONCLUSION

Applicant submits that the present application is in condition for allowance and requests early allowance of the pending claims.

The Commissioner is hereby authorized to charge any under payment or credit any over payment to Deposit Account No. 19-1345.

Respectfully submitted,



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